K113389

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	November 1, 2011	
Device:	Trade Name: System	ACE Axcel Clinical Chemistry
	Classification:	Class 1
	Common/Classification Name:	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use (21 C.F.R. § 862.2610) Product Code JJE
	Trade Name:	ACE BUN/Urea Reagent
	Classification:	Class 2
	Common/Classification Name: Nitrogen	Urease, Photometric, Urea (21 C.F.R. § 862.1770) Product Code CDN
	Trade Name:	ACE Creatinine Reagent
	Classification:	Class 2
	Common/Classification Name:	Alkaline Picrate, Colorimetry, Creatinine (21 C.F.R. § 862.1225) Product Code CGX
	Trade Name:	ACE Uric Acid Reagent
	Classification:	Class 1
	Common/Classification Name:	Acid, Uric, Uricase (Colorimetric) (21 C.F.R. § 862.1775) Product Code KNK

	Trade Name:	ACE CK Reagent
	Classification:	Class 2
	Common/Classification Name:	NAD Reduction/NADH Oxidation, CPK Or Isoenzymes (21 C.F.R. § 862.1215) Product Code CGS
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE Clinical Chemistry System, Calibrators, Chemistry Controls, plus 12 ACE Reagents (K930104)	
Device Descriptions:	The ACE Axcel Clinical Chemistry System consists of two major components, the chemistry instrument and an integrated Panel PC. The instrument accepts the physical patient samples, performs the appropriate optical or potentiometric measurements on those samples and communicates that data to an integral Panel PC. The Panel PC uses keyboard or touch screen input to manually enter a variety of data, control and accept data from the instrument, manage and maintain system information and generate reports relative to patient status and instrument performance. The Panel PC also allows remote download of patient requisitions and upload of patient results via a standard interface. In the ACE BUN/Urea Reagent assay, urea in serum is hydrolyzed to yield ammonia and carbon dioxide in the presence of urease. The ammonia formed then reacts with 2-oxoglutarate and NADH in the presence of glutamate dehydrogenase to yield glutamate and NAD. Two moles of NADH are oxidized for each mole of urea present. NADH absorbs strongly at 340 nm, whereas NAD^+ does not. The initial rate of decrease in absorbance, monitored bichromatically at 340 nm/647 nm, is proportional to the urea concentration in the sample. In the ACE Creatinine Reagent assay, creatinine reacts with picric acid in an alkaline medium to form a red-orange colored complex, which absorbs strongly at 505 nm. The rate of complex formation, determined by measuring the increase in absorbance bichromatically at 505 nm/573 nm during a fixed time interval, is directly proportional to the creatinine concentration in the sample. In the ACE Uric Acid Reagent assay, uric acid in serum is oxidized by uricase to allantoin and hydrogen peroxide. The hydrogen peroxide then acts to oxdatively couple dichlorohydroxybenzene sulfonic acid and 4-aminoantipyrine in a reaction catalyzed by peroxidase, producing a red colored quinoneimine complex, which absorbs strongly at 505 nm. The amount of chromogen formed, determined by	

	measuring the increase in absorbance bichromatically at 505 nm/610 nm, is directly proportional to the uric acid concentration in the sample. In the ACE CK Reagent assay, serum creatine kinase initiates the conversion of creatine phosphate to creatine with the transfer of a phosphate group to adenosine diphosphate (ADP), forming ATP. The ATP is then used in the phosphorylation of D-glucose to form D-glucose-6-phosphate and ADP. This reaction is catalyzed by hexokinase. The enzyme glucose-6-phosphate dehydrogenase catalyzes the reduction of D-glucose-6-phosphate and nicotinamide adenine dinucleotide phosphate ($NADP^+$). The series of reactions triggered by serum creatine kinase and ending in the formation of NADPH. NADPH strongly absorbs at 340 nm, whereas $NADP^+$ does not. Therefore, the rate of conversion of $NADP^+$ to NADPH can be determined by monitoring the increase in absorbance bichromatically at 340 nm/378 nm. This rate of conversion from $NADP^+$ to NADPH is a function of the activity of CK in the sample.
Intended Use:	Indications for Use: The ACE BUN/Urea Reagent is intended for the quantitative determination of blood urea nitrogen (BUN) concentration in serum using the ACE Axcel Clinical Chemistry System. BUN measurements are used in the diagnosis and treatment of certain renal and metabolic diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Creatinine Reagent is intended for the quantitative determination of creatinine concentration in serum using the ACE Axcel Clinical Chemistry System. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Uric Acid Reagent is intended for the quantitative determination of uric acid concentration in serum using the ACE Axcel Clinical Chemistry System. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients receiving cytotoxic drugs. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

	The ACE CK Reagent is intended for the quantitative determination of creatine kinase activity in serum using the ACE Axcel Clinical Chemistry System. Measurement of creatine kinase is used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.
Technological Characteristics:	The following is a description of the major features of the ACE Axcel Clinical Chemistry System: • System throughput is approximately 160 test results per hour for routine, single reagent chemistries. System throughput will be higher when the test workload includes ISE's. • The instrument has a capacity of 40 reagent containers on board. A reagent cooling system maintains the reagents at 12°C during instrument operation. • Reagent containers are identified by computer coded labels to simplify system operation. All reagents in the system must include an identification label on the container. • Sample and reagent sensing notify the operator of a depleted condition during operation. • The system performs analysis at a reaction temperature of 37°C. • An electrolyte subsystem capable of measuring sodium, potassium and chloride concentrations is included. • Primary draw tubes may be introduced one at a time into the system for closed tube sampling. Positive tube identification can be achieved with an optional barcode scanner. An aliquot volume sufficient for all tests ordered is transferred and stored and the closed tube is returned to the user. • Sample cups are introduced to the system one at a time or by sample ring segment. • Disposable cuvettes are loaded in bulk and then automatically injected as needed by a cuvette hopper system. The ACE Axcel clinical chemistry optical system is capable of monitoring a maximum of 48 cuvettes at one time. • The absorbance optical system is capable of absorbance measurements in a linear range of 0.0 to 2.0 absorbance units (at 0.67 cm pathlength). Sixteen wavelengths are measured simultaneously using a photodiode array. The ACE BUN/Urea Reagent consists of a single reagent bottle. The reagent contains α-ketoglutarate, urease, glutamate dehydrogenase, adenosine diphosphate (ADP), nicotinamide adenine dinucleotide and reduced (NADH).

	The ACE Creatinine Reagent consists of two reagent bottles (Sodium Hydroxide Reagent and Picric Acid Reagent). The Sodium Hydroxide Reagent (R1) contains sodium hydroxide. The Picric Acid Reagent (R2) contains picric Acid. The ACE Uric Acid Reagent consists of a single reagent bottle. The reagent contains 4-aminoantipyrine, dichlorohydroxybenzene sulfonic acid, peroxidase and uricase. The ACE CK Reagent consists of two reagent bottles (Buffer and Substrate). The Buffer Reagent (R1) contains: imidazole buffer, glucose, N-acetyl-cysteine, magnesium acetate, EDTA, NADP and hexokinase. The Substrate Reagent (R2) contains: creatine phosphate, ADP, AMP, diadenosine pentaphosphate, EDTA and glucose-6-phosphate dehydrogenase.
Performance Data:	Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Axcel Clinical Chemistry System included precision, accuracy, and detection limit data. ACE BUN/Urea Reagent Precision: In testing conducted at four BUN levels for 22 days, the within-run CV ranged from 1.1 to 3.3%, and total CV ranged from 3.5 to 4.6%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.0 to 2.6% and total CV ranged from 3.0 to 5.2%. Accuracy: In the correlation study, 113 samples with BUN values ranging from 4 to 96 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9963, a standard error estimate of 1.5, a confidence interval slope of 0.995 to 1.028, and a confidence interval intercept of -0.3 to 0.6. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9982 to 0.9988, standard error estimates of 1.0 to 1.6, confidence interval slopes of 0.983 to 1.039, and a confidence interval intercepts of -0.7 to 1.6. Detection limit: The detection limit was 1.1 mg/dL.

ACE Creatinine Reagent

Precision: In testing conducted at four creatinine levels for 22 days, the within-run CV ranged from 1.3 to 9.6%, and total CV ranged from 2.7 to 9.8%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.9 to 5.1% and total CV ranged from 2.1 to 6.1%.

Accuracy: In the correlation study, 136 samples with creatinine values ranging from 0.28 to 22.95 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9998, a standard error estimate of 0.082, a confidence interval slope of 0.975 to 0.983, and a confidence interval intercept of -0.022 to 0.010. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9994 to 0.9998, standard error estimates of 0.123 to 0.192, confidence interval slopes of 0.961 to 1.027, and a confidence interval intercepts of -0.136 to 0.001.

Detection limit: The detection limit was 0.19 mg/dL.

ACE Uric Acid Reagent

Precision: In testing conducted at four uric acid levels for 22 days, the within-run CV ranged from 1.8 to 4.9%, and total CV ranged from 2.0 to 5.4%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 1.5 to 4.4% and total CV ranged from 1.8 to 5.2%.

Accuracy: In the correlation study, 106 samples with uric acid values ranging from 1.7 to 15.9 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9958, a standard error estimate of 0.23, a confidence interval slope of 1.023 to 1.060, and a confidence interval intercept of -0.18 to 0.07. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9858 to 0.9961, standard error estimates of 0.22 to 0.44, confidence interval slopes of 0.972 to 1.054, and a confidence interval intercepts of -0.31 to 0.28.

Detection limit: The detection limit was 1.13 mg/dL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 10 2012

Alfa Wassermann Diagnostic Technologies, LLC
c/o Hyman Katz, Ph.D.
Vice President, Quality and Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

Re: k113389
Trade/Device Name: ACE BUN Reagent, ACE Creatinine Reagent, ACE Uric Acid Reagent, ACE CK Reagent
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDN, CGX, KNK, CGS
Dated: July 31, 2012
Received: August 1, 2012

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113389

Device Name: ACE BUN/Urea Reagent

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Device Name: ACE Creatinine Reagent

Indications for Use: The ACE Creatinine Reagent is intended for the quantitative determination of creatinine concentration in serum using the ACE Axcel Clinical Chemistry System. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In vitro* Diagnostic Devices (OIVD)

Division Sign-Off
Office of *In vitro* Diagnostic Device
Evaluation and Safety

510(k) K113389

Indications for Use

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Device Name: ACE Uric Acid Reagent

Indications for Use: The ACE Uric Acid Reagent is intended for the quantitative determination of uric acid concentration in serum using the ACE Axcel Clinical Chemistry System. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions and of patients receiving cytotoxic drugs. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE CK Reagent

Indications for Use: The ACE CK Reagent is intended for the quantitative determination of creatine kinase activity in serum using the ACE Axcel Clinical Chemistry System. Measurement of creatine kinase is used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of *In vitro* Diagnostic Devices (OIVD)

Division Sign-Off
Office of *In vitro* Diagnostic Device
Evaluation and Safety

510(k) 113389